

RESULTS OF INVESTIGATION: The 14-vial lot was the "*Laetrile*" product which had been relabeled by the dealer as "*Formula L.*"

LIBELED: 12-28-60, N. Dist. Tex.

CHARGE: 505(a)—the article was a new drug which may not be introduced into or delivered for introduction into interstate commerce since it was sold for investigational purposes and was not being so used, and an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: 2-7-61. Default—delivered to the Food and Drug Administration.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

DRUG FOR HUMAN USE

6544. Penicillin G tablets. (F.D.C. No. 45448. S. No. 26-857 R.)

QUANTITY: 43 100-tablet btls. at Los Angeles, Calif.

SHIPPED: 8-16-60, from Philadelphia, Pa., by Philadelphia Ampoule Laboratories.

LIBELED: 3-8-61, S. Dist. Calif.

CHARGE: 502(1)—when shipped, the article was composed in whole or in part of penicillin and was from a batch with respect to which a certificate or release had not been issued pursuant to 507 in that effective exemption or supplemental certification of the batch had not been obtained.

DISPOSITION: 3-30-61. Default—destruction.

DRUG FOR VETERINARY USE

6545. Dihydrostreptomycin tablets. (F.D.C. No. 45511. S. No. 61-028 R.)

QUANTITY: 3 drums, each containing 11,500 tablets, 1 drum containing 600 tablets, and 125 100-tablet btls., at St. Joseph, Mo., in possession of United Pharmacal Co., Inc.

SHIPPED: 7-30-58, from Buffalo, N.Y.

LABEL IN PART: (Drum) "Special Formula S/F Tablets—Uncoated Expiration Date July 1960 7-30-58 Manufactured for United Pharmacal Co. * * * St. Joseph, Missouri * * * Formula No. 159,700 Lot 1 UPC-1 * * * Each tablet contains: Dihydrostreptomycin Base (as Sulfate) 50 mg. Pectin 37 mg. Kaolin 417 mg. Hydrated Alumina Powder 126 mg. For treatment of gastroenteritis, enteritis and diarrhea (due to dihydrostreptomycin sensitive organisms) in cats and dogs" and (btl.) "UPCO * * * 'K.P.S.-630' Dihydrostreptomycin Sulfate with Kaolin, Alumina, and Pectin. Each tablet contains * * * Distributed by United Pharmacal Company, St. Joseph, Mo."

RESULTS OF INVESTIGATION: The article in the bottles was repacked and labeled by the dealer after shipment as described above.

LIBELED: On or about 3-16-61, W. Dist. Mo.

CHARGE: 502(1)—while held for sale, the article purported to be and was represented as a drug composed in part of dihydrostreptomycin and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507.

DISPOSITION: 5-5-61. Default—destruction.